

Bone Dust Trap – BDT

Instructions for Use

Caution: Strictly following this Instructions for Use document is required to ensure safety and efficiency of the device use. Failure to follow the instructions, warnings and cautions specified in this document may result in device malfunction and compromising safety of the patient.

Device Description

Sterile disposable, intraoperative graft recovery system comprising a cylindrical container and a lid with integrated element of a dual stage filtration system. Connection to the vacuum source through suction tubing is required to use the device. The Bone Dust Trap does not contain latex.

Indications for Use

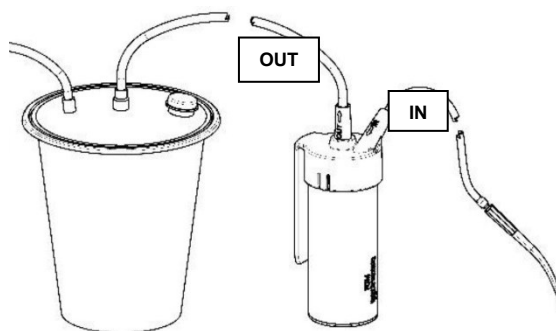
The Bone Dust Trap is intended to capture and retain bone dust and fragments during various surgical procedures. Connected to the vacuum source in-line with suction tubing, the Bone Dust Trap separates bone fragments from the surgical site fluids and captures the autologous bone graft on the filtrating surfaces for further use in bone grafting procedures.

Directions for Use

To use the Bone Dust Trap:

1. Cut the vacuum source suction tubing, adjusting the length to keep the device within the aseptic area. Connect an outlet port marked “OUT” to the vacuum source through the suction tubing. Make sure that connection is sealed properly. Connect an inlet port marked “IN” to the suction tubing with a tip leading to the operating site as shown on Figure 1.

Figure 1

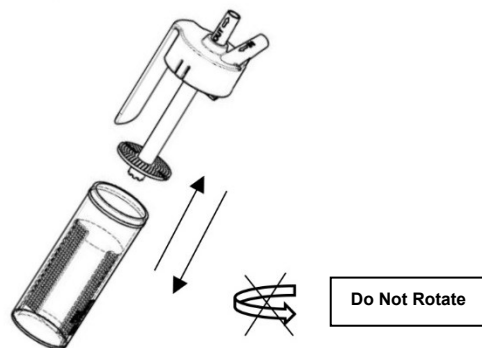


2. Place the Bone Dust Trap into a draping pouch vertically and secure with a fixation clip.

3. Once the device is filled, disconnect the outlet port of the device from the suction tubing of the vacuum source.
4. To open the device, pull the lid out holding inlet and outlet ports with your fingers. Do not rotate the lid - Figure 2.

Warning: rotation of the lid may cause device damage and malfunction.

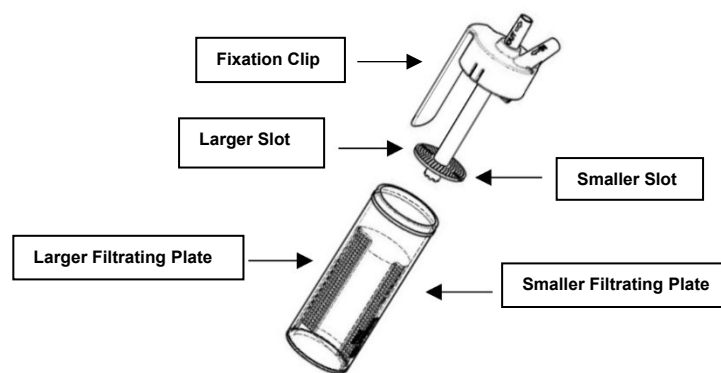
Figure 2



5. Remove collected bone graft. The device can be used up to 3 (three) times in total, providing three collection cycles during single operating procedure on the same patient.
6. After emptying the device, place the lid back. Make sure that the size of the slots on the filtrating membrane corresponds to the size of the filtrating plates, located along the inner walls of the cylindrical container.

Note: The larger slot and the fixation clip are located on the same side of the device (Figure 3).

Figure 3



Caution

US Federal law restricts this device to sale by or on the order of a physician only.

To ensure maximum efficiency, the device should be positioned in the draping pouch vertically.

Instructions for use must be followed exactly to ensure the device operates as intended.

Contraindications

General contraindication to the surgical procedure.

Absolute contraindications include infection, sepsis, and osteomyelitis and malignant disease (risk of surgical dissemination).

Warning

- It is the responsibility of a surgeon and a surgical team to be trained to apply proper techniques for using the Bone Dust Trap. Improper use of the device may cause serious injury to operator or patient and/or cause damage to the device.
- The Bone Dust Trap is a disposable device. Re-sterilization is strictly prohibited and may cause patient contamination and device malfunction.
- Eye protection is compulsory while using the Bone Dust Trap.
- Before use, inspect the packaging and the device. Visually inspect the packaging for any signs of damage including packaging puncture, tear any other damage. Do not use the Bone Dust Trap if the packaging is compromised. Sterility is guaranteed unless the packaging is damaged or open.
- Inspect the Bone Dust Trap for any damage. Do not use if the device has any signs of damage.
- Do not connect the device to high suction units. Maximum negative pressure for the Bone Dust Trap use is 21in Hg.
- Remove the device from the patient in case of defibrillation.

Cleaning and Sterilization

The Bone Dust Trap is a single patient use only, sterile disposable device. Reuse or re-sterilization of the device is strictly prohibited.

Disposal

Dispose of the device according to the federal, state and local regulations.

Warranty

RIM Medical Technologies will not accept any returns of the devices that have been in contact with the patient blood and body fluids.

Please contact your local representative or distributor for information on return and exchange.

Symbols

	Keep Dry		Sterile unless Packaging is Damaged or Open
	Use Before		Batch Code
	Single Use		Catalog Name
	Sterilized Using Irradiation		Consult Instructional Manual
	Medical Device		Manufacturer
	Do Not Rotate		Direction pointing arrows
	Caution		Do not reserialize



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